

**Notice of Proposed Rulemaking
For
Title 16. California Code of Regulations
Division 40. Bureau of Naturopathic Medicine**

NOTICE IS HEREBY GIVEN that the Bureau of Naturopathic Medicine (Bureau), within the Department of Consumer Affairs, is proposing to take the action described in the Informative Digest. Any person interested may present statements or arguments orally or in writing relevant to the action proposed at a hearing to be held as follows:

Date: February 23, 2005
Time: 10:00 a.m.
Location: 400 R Street, 1st Floor Hearing Room
Sacramento, CA 95814

Written comments, including those sent by mail, facsimile, or e-mail, must be addressed to the person listed under Contact Person in this Notice and must be received by the Bureau at its office not later than 5:00 p.m. on February 22, 2005 or received by the Bureau at the hearing. The Bureau, upon its own motion or at the instance of any interested party, may thereafter adopt the proposals substantially as described below or may modify such proposals if such modifications are sufficiently related to the original text. With the exception of technical or grammatical changes, the full text of any modified proposal will be available for public comment 15 days prior to its adoption and can be obtained from the person designated in this Notice as the contact person. Furthermore, the modified proposal will be mailed to those persons who submit written or oral testimony related to this proposal or who have requested notification of any changes to the proposal.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW

Prior to the enactment of Senate Bill (SB) 907 (Chapter 485, Statutes of 2003), which is known as the Naturopathic Doctors Act (Act), the practice of naturopathic medicine was not regulated in California. However, the passage of SB 907 established the Bureau with the responsibility of licensing naturopathic doctors and enforcing the provisions of the Act. SB 907 creates a two-step implementation process: First, on or after January 1, 2004, the Bureau is authorized to establish fees for licensure and collect the appropriate fees. Secondly, on or after July 1, 2004, the Bureau shall administer and enforce the provisions of the Act.

These regulations enable the Bureau to meet both statutory obligations by specifying the contents of the application, the application and license renewal processes, and the appropriate fees for a naturopathic doctor's license. The funds collected from applicants will allow the Bureau to commence its administrative and enforcement responsibilities after July 1, 2004. In addition, the adoption of these regulations will make specific the following:

- minimum education and examination requirements for licensure;
- allowable and non-allowable functions as a licensed naturopathic doctor, including furnishing and ordering drugs;
- notice to potential licensees of the scope of unprofessional conduct that will result in

- disciplinary actions against his or her license;
- establish the authority to issue citations, specify citation processes, and establish administrative fines for citations;
- establish timelines to meet compliance with an order of abatement, as well as specifying the activities of unlicensed practice;
- set guidelines for public disclosure of information regarding licensed naturopathic doctors;
- address that the authority of the law relating to naturopathic corporations does not alter the responsibilities of a naturopathic doctor to his or her patients; and
- sets standards for naturopathic corporation insurance policies as well as naturopathic corporations' shares ownership and transfer.

AUTHORITY AND REFERENCE:

Pursuant to the authority vested by sections 104, 125.9, 142, 144, 148, 480, 481, 482, 700-704, 3620, 3622, 3623, 3630, 3671, 3675, 3680, and 3685 to make specific and interpret sections 104, 122, 125.9, 142, 144, 148, 480, 481, 482, 651, 700-704, 3610, 3620, 3623, 3624, 3630, 3631, 3633.1, 3634, 3635, 3636, 3640.5, 3650, 3651, 3651.5, 3652, 3662, 3663, 3670, 3671, 3672, 3673, 3674, 3675, 3680 and 3685 of the Business and Professions Code; Section 11164 of the Health and Safety Code; Section 6253 of the Government Code, and Sections 13401 and 13401.5 of the Corporations Code, the Bureau within the Department of Consumer Affairs proposes the adoption of a Division 40 of Title 16 of the California Code of Regulations, as follows:

Specific Description of Proposed Regulations

This regulatory action adds Division 40 to Title 16 of the California Code of Regulations. Specifically, this regulatory action:

Article 1. General Provisions

1. Adds Section 4200.

This section establishes the purpose of these regulations – to implement and make specific the statutory provisions of the Naturopathic Doctors Act.

2. Adds Section 4202.

This section specifies that the principal office of the Bureau is located in Sacramento, California.

3. Adds Section 4204.

This section requires persons issued a certificate or license by the Bureau to: 1) notify the Bureau of his or her current address and 2) notify the Bureau within fourteen (14) days of any changes of address.

4. Adds Section 4206.

This section establishes the regulatory definition of various terms.

5. Adds Section 4208.

This section establishes the conditions under which the Bureau will disclose complaint information.

Article 2. Applications

6. Adds Section 4210.

This section specifies that completed applications for licensure or certification are to be filed at the Bureau's principal office in Sacramento.

7. Adds Section 4212.

This section specifies the contents of an application for licensure as a naturopathic doctor and also specifies that the application fee is not refundable.

8. Adds Section 4214.

This section specifies the contents of an application for a certificate of registration and the duration of said certificate, and the renewal process for the certificate.

9. Adds Section 4216.

This section specifies that the Bureau shall notify applicants as to the completeness of their application within one hundred (100) working days of receipt. This section also specifies that within one hundred (100) working days of the filing of a complete application, the Bureau shall notify applicants whether the application has been approved or denied.

10. Adds Section 4218.

This section specifies under which conditions applications filed with the Bureau may be considered abandoned and that upon abandonment, the application fee is forfeited to the Bureau.

Article 3. Examinations

11. Adds Section 4220.

This section establishes the Naturopathic Physicians Licensing Examination (NPLEX) as the licensing examination.

Article 4. Licenses

12. Adds Section 4222.

This section specifies that the duration of a license is two years from the last day of the second birth month and establishes the requirements for license renewal.

13. Adds Section 4224.

This section specifies that a naturopathic doctor's license must be displayed under glass or other transparent material in an area frequented by patients.

14. Adds Section 4226.

This section specifies the requirements for a licensee to renew an expired license or certificate and the fees required for renewal.

15. Adds Section 4228.

This section specifies the requirements for a license to be placed on inactive status.

Article 5. Schools

16. Adds Section 4230.

This section addresses approval of naturopathic medical schools. Naturopathic medical schools that have been accredited by the California Naturopathic Medical Education are deemed approved by the Bureau. This section also requires the Bureau to maintain a list of approved schools.

Article 6. Practice of Naturopathic Medicine

17. Adds Section 4232.

This section specifies the requirements for giving a patient informed consent.

18. Adds Section 4234.

This section specifies that scope of the medical services that a licensed naturopathic doctor may provide or perform.

19. Adds Section 4236.

This section establishes the requirements for a licensed naturopathic doctor to prescribe drugs. This section also specifies the requirements for a drug order issued by a naturopathic doctor.

Article 7. Fees

20. Adds Section 4240.

This section establishes the fees that are required for applications, initial licensure, renewal of a current or expired license, duplicate licenses and the fee for processing fingerprint cards.

Article 8. Citations

21. Adds Section 4242.

This section establishes the authority to issue citations and timeframes for purging a citation. Also specifies that citations will be disclosed to the public upon request.

22. Adds Section 4244.

This section specifies the format of a citation and the process for issuing a citation.

23. Adds Section 4246.

This section establishes minimum and maximum amounts for the administrative fines contained in a citation.

24. Adds Section 4248.

This section specifies the factors that the Chief of the Bureau shall consider in assessing the amount of an administrative fine.

25. Adds Section 4250.

This section establishes the process for contesting a citation and establishes that a person issued a citation that has had the citation modified in an informal conference cannot request another informal conference to contest the same citation.

26. Adds Section 4252.

This section establishes the timeframes for complying with an order of abatement and specifies the consequences of failing to honor those timeframes.

27. Adds Section 4254.

This section establishes the authority for the Bureau to issue citations for unlicensed activity and fine amounts of such citations.

Article 9. Enforcement

28. Adds Section 4256.

This section defines the substantial relationship criteria for the Bureau to use when denying, suspending, or revoking a license based upon an act or crime committed by an applicant or licensee.

29. Adds Section 4258.

This section establishes the criteria that the Bureau must follow when considering the denial of a license or when evaluating the rehabilitation of the applicant.

30. Adds Section 4260.

This section defines unprofessional conduct for which the Bureau may take disciplinary action against a licensee.

Article 10. Advertising

31. Adds Section 4262.

This section authorizes licensees to advertise naturopathic medical services with the specified restrictions.

Article 11. Naturopathic Corporations

32. Adds Section 4264.

This section establishes that the authority of the laws relating to naturopathic corporations does not alter the responsibilities of a naturopathic doctor to his or her patients.

33. Adds Section 4266.

This section sets standards for naturopathic corporation insurance policies and establishes the liability of the shareholders of a naturopathic corporation under specified conditions.

35. Adds Section 4268.

This section establishes the requirements of ownership and transfer of ownership of the shares of a naturopathic corporation.

ADOPTING OR AMENDING REGULATIONS MANDATED BY FEDERAL LAW OR
FEDERAL REGULATIONS: None

LOCAL MANDATE: The Bureau has determined the adoption of these regulations does not impose a mandate on local agencies or school districts.

FISCAL IMPACT:

1. Cost to Any Local Agency or School District for Which Government Code Section 17500-17630 Requires Reimbursement: None.
2. Other non-discretionary cost or savings imposed upon local agencies: None
3. Costs or savings to any state agency. Bureau expenditures are estimated at \$280,000 for fiscal years 2004/05 and 2005/06. Licensing revenue is estimated at \$340,000 for fiscal years 2004/05 and 2005/06.
4. Costs or savings in federal funding to the state: None

EFFECT ON HOUSING COSTS: None

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING ABILITY TO COMPETE: The Bureau has made an initial determination that the adoption of these regulations will not have any significant adverse economic impact on businesses.

ASSESSMENT REGARDING EFFECT ON JOBS/BUSINESS: Adoption of these regulations will authorize the Bureau to license individuals as naturopathic doctors, which will create new jobs in the healthcare industry and will allow consumers to expand their health care options. Additionally, if new licensees choose to establish offices, then office support and medical assistant jobs may also be created.

COST IMPACT ON REPRESENTATIVE PRIVATE PERSON OR BUSINESS: The Bureau estimates that approximately 200 persons will initially seek licensure. For those persons who wish to be licensed as a naturopathic doctor, a \$400 application fee and an \$800 license fee will be set upon the adoption of the regulations. Other fees set within these regulations include \$800 biennial renewal fee; \$150 late renewal fee; and \$25 for a duplicate naturopathic doctor's license. In addition, applicants will have to pay fingerprinting fees for California Department of Justice (DOJ) and the Federal Bureau of Investigation (FBI) criminal records check. These fees average about \$66.00 (\$32.00 for DOJ, \$24.00 for FBI, and usually \$10.00 for rolling fee; however, the rolling fees may be higher or lower depending on the site conducting the services).

EFFECT ON SMALL BUSINESS: The Bureau has determined that the proposed regulations would not affect existing small businesses because the Bureau will be licensing individuals and not businesses. However, as noted above under ASSESSMENT REGARDING EFFECT ON JOBS/BUSINESS, new licensees may choose to establish offices, which may result in the employment of office staff such as office manager, clerical support, and medical assistants.

CONSIDERATION OF ALTERNATIVES: The Bureau must determine that no reasonable alternative it considered or that has otherwise been identified and brought to its attention would either be more effective in carrying out the purpose for which these regulations has proposed or would be as effective and less burdensome to affected private persons than these proposed regulations in this Notice.

Any interested person may present statements or arguments orally or in writing relevant to the above determinations at the above-mentioned hearing.

CONTACT PERSON: Any inquiries or comments concerning the proposed rulemaking action may be addressed to:

Name: Joanne Davis
Address: Department of Consumer Affairs
Bureau of Naturopathic Medicine
400 R Street, Suite 3030, Sacramento, CA 95814
Telephone No.: (916) 445-8692
TDD No.: (916) 322-1700
E-Mail Address: naturopathic@dca.ca.gov
(Type in "Regulatory Comment" in Subject line.)

The backup contact person is:

Name: Kathy McKeever
Address: Department of Consumer Affairs
Bureau of Naturopathic Medicine
400 R Street, Suite 3030, Sacramento, CA 95814
Telephone No.: (916) 445-8692
E-Mail Address: naturopathic@dca.ca.gov
(Type in "Regulatory Comment" in Subject line.)

BUREAU WEBSITE: Materials regarding this proposal can be found at the Bureau's website at www.naturopathic.ca.gov.

AVAILABILITY OF STATEMENTS: Copies of the of the proposed regulations, the Initial Statement of Reasons, and all of the information upon which the proposal is based, can be obtained through the Bureau's website at www.naturopathic.ca.gov; at the hearing or prior to the hearing; or upon request by contacting the Bureau at the address and phone numbers listed above.

AVAILABILITY AND LOCATION OF THE FINAL STATEMENT OF REASONS AND RULEMAKING FILE: All the information upon which the proposed regulations are based is contained in the rulemaking file which is available for public inspection by contacting the person named above. You may obtain a copy of the Final Statement of Reasons once it has been prepared, by making a written request to the contact person named above or by accessing the Bureau's website at www.naturopathic.ca.gov.